United Egg Producers

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July 25, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: [Docket No. 20000N-0504] (formerly Docket No. 00N-0504)

Dear Sir or Madam:

These comments are submitted on behalf of United Egg Producers (UEP). UEP is a farm cooperative whose members account for some 90 percent of shell egg production in the United States. We appreciate the opportunity to submit additional comments on the Food and Drug Administration's (FDA) proposed rule of September 22, 2004, entitled "Prevention of Salmonella Enteritidis in Shell Eggs During Production." We previously filed extensive comments on the proposed rule.

In the Federal Register of May 10, 2005, FDA reopened the comment period for the proposed rule to receive comments and other information regarding industry practices and programs that prevent SE–monitored chicks from becoming infected by SE during the period of pullet rearing until placement into laying hen houses. Beginning in May, UEP conducted a survey of shell egg producers to obtain answers to the questions posed by FDA. In these comments we have compiled information from the survey that responds to the Agency's request without revealing data that would identify individual firms.

We appreciate and strongly support FDA in seeking as much information as possible about current industry practices to control SE before publishing a final rule. A thorough analysis of the issue will result in a more effective program that can be applied in the most practical manner and assure the safety of eggs produced in the United States.

The UEP survey included a series of questions designed to elicit the information FDA indicated it was seeking in the May 10 Federal Register notice. Some 42 UEP members responded to the

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survey. The 40 respondents that included the number of layers on their farms collectively represent 105 million egg laying hens, over 40 percent of the total U.S. layer industry. The nation's total flock size, including flocks producing eggs for table use and those dedicated to producing eggs for further processing into egg products, is 285 million birds. While the survey was anonymous, certain identifying information indicated that surveys were submitted by firms producing primarily for the table egg market as well as companies whose production is largely dedicated for egg breaking and processing into pasteurized liquid, frozen, and dried egg products. The average number of hens owned by each of these producers is 2.6 million, somewhat higher than the national average. Producer size ranged from 130,000 owned by the smallest to in excess of 10 million birds owned by the largest.

Not all producers that returned the surveys provided complete answers to every question. In using survey results to prepare these comments, only complete and valid responses to the question asked were considered. For clarity, we have repeated in bold type below each question raised by FDA in the May 10 Federal Register notice, followed by a discussion of the survey response for that question.

1. How many pullet growing facilities are there in the United States? What is the range in the number of houses on those facilities?

The survey asked producers to identify the source of pullets for their layer farms. The vast majority of respondents secure pullets from company owned grow-out facilities. These producers own 258 pullet houses with a total annual grow out capacity of 52 million pullets. (Since the majority of birds have over a 2-year life span, required pullet rearing capacity is only about half of total layer flock size.) On average, each company has 6 houses, with the actual number per company ranging from 1 house to 38 houses. In many cases, more than one house is located on the same geographic site. Respondents indicated that they purchase an additional 3 million pullets each year from commercial pullet grow-out firms.

An extrapolation of the numbers compiled by the survey from respondents with 258 barns representing 40 percent of U.S. egg production suggest there may be approximately 700 producer-owned pullet rearing barns in the United States.

One commercial pullet rearing facility responded to the survey. This respondent did not indicate total capacity, but reported 11 houses. This firm described its cleaning and disinfection, biosecurity, testing, and vaccination programs and we have included this information in preparing responses to subsequent questions. The 42nd respondent indicated that it acquires pullets only from a commercial pullet growing firm and we have not included any information from that respondent in subsequent answers.

***What percentage of pullet growers are under programs or have practices aimed at preventing SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into layer hen houses?**

All 41 respondents (40 producers and one commercial pullet grower) have implemented practices aimed at preventing infection of SE-monitored chicks by SE during the period of pullet

rearing. Of this number, 39, including the commercial provider, follow a state, industry, or company egg quality assurance program (EQAP) directed at preventing SE. Of the two producers that indicated they do not follow an EQAP, one nevertheless described preventative measures comparable to those in the formal EQAPs. The other producer has vaccination and biosecurity programs, but does not perform any testing.

***Do State or regional Egg Quality Assurance Programs include provisions to prevent SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into layer hen houses?**

In their responses, 28 said that the EQAPs they follow include provisions to prevent infection of SE-monitored chicks during pullet rearing. Nine responded no to this question. However, some of the responses appear to be in error or the question was misunderstood because other respondents following the same EQAP indicate that it does include such provisions.

***How effective have the pullet programs (whatever the programs entail – cleaning, testing, etc.) been in reducing the prevalence of SE in layer flocks? How is effectiveness measured?**

The programs appear to be highly effective, as demonstrated by the presence or absence of SE. Twenty six of the respondents provided information on testing they have employed to determine whether SE is present in their pullets. In 25 instances, testing beyond chick papers was reported. The tests include environmental testing (for example, equipment or manure) and tests of birds or organs, any of which may occur between 4 and 15 weeks of age. One reported bird testing whenever signs of disease are observed.

Results of the testing programs are discussed in greater detail in the response to question 2.

2. During pullet rearing, what programs or industry practices are currently taken to prevent SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into layer hen houses?

Following are practices currently employed to prevent SE infection of pullets:

Chicks - All respondents reported that they acquire SE-monitored chicks from flocks participating in the National Poultry Improvement Plan (NPIP).

Cleaning and Disinfection – All respondents reported that they clean and disinfect before each new pullet flock.

Biosecurity Measures – All but two respondents reported extensive biosecurity measures. One of the two did not address this question and the other reported only minimal biosecurity measures. These include one or more of the following:

Employee measures –

- Uniform or other clothing restricted to the work site only

- Prohibition against bird contact outside the work site
- Foot baths
- Employee movement between work sites (houses, processing plants, etc.) at the facility is restricted
- Showering in
- Training

Equipment measures –

- Cleaning and disinfection of equipment
- Equipment is not shared between houses
- Washing of transportation vehicles

Measures to prevent entry by wild birds –

- Screens on air intakes and other openings
- Monitoring and measures to prevent bird nest building
- Quick removal of feed spills

Pest and rodent control -

- Bait stations
- Type of baits are varied
- Monitoring programs with adjustments in program as necessary

While most respondents have extensive biosecurity programs, not all of the respondents reported employing all of these practices.

***Are pullets or their environment tested for SE between the time they are procured as chicks and the time they enter layer houses? If so, when? When tested, approximately how often do pullets or pullet environments test positive? What happens after a positive test?**

All respondents secure chicks from National Poultry Improvement Plan SE-monitored breeder flocks and 26 test chick papers at or shortly after receipt of the SE-monitored chicks. Additional testing at chick placement or later in the rearing cycle is practiced by 24 of the respondents. Environmental or bird testing is generally conducted at 15 weeks of age, but one tests as early as 4 weeks and another just prior to placement in the layer house.

Of those respondents indicating that they test chick papers and perform subsequent or simultaneous environment or organ testing, seven reported that they have had positive environmental samples. Twenty reported that they have not encountered positive environmental or organ samples. Of the seven firms reporting positives –

- Two had them a number of years ago, but none in recent years.
- One reported none have been found since implementation of a vaccination program.
- One respondent has identified SE in houses only before cleaning and disinfection.

- Another respondent noted that the farm has encountered only one environmental positive.

Respondents described actions they have taken upon a positive environmental sample and many included actions in plan that would be taken if a positive sample is found. These actions include-

- Depopulation
- Movement to a farm dedicated to production for egg breaking
- Retesting
- Vaccination
- Additional cleaning and disinfection

***Is vaccination uses as preventative measure, if so, when and how?**

Vaccination is used as a preventative measure by 31 or 78 percent of the respondents that answered this question. The one commercial grow-out firm that responded to the survey has a strict regimen for vaccination. Therefore, some of the nine respondents answering no to this question no doubt receive vaccinated pullets. Attenuated live vaccine alone is used by 19 of the firms, killed alone by 2, and both programs are employed by 9 respondents. One respondent that vaccinates did not describe the protocol.

Of those who administer the live vaccine, they generally give 1-3 doses at different ages during the rearing cycle, with most giving at least 2-3 doses. The time of vaccination varies by producer with some giving the first dose to day old chicks and others administering the first dose as late as 4 weeks. The last dose is as late as 16 weeks and a few indicated that the last dose in a three dose series is given prior to molt in the layer house. None reported giving the initial dose after placement in the layer house, indicating vaccination is normally part of a pullet house SE prevention program as well as providing protection during the laying cycle.

The killed vaccine is administered in a single dose between 9-16 weeks with most between 12-14 weeks.

Analysis of individual survey results indicates that a strong vaccination program is a major part of the control program in the pullet house, particularly for those farms producing for the table egg market. U.S. producers positive experience with vaccination – at both pullet and layer stages of growth – mirrors that in the United Kingdom (U.K.), where vaccination is a requirement of that nation's successful Lion Program. A recent study by the U.K.'s Food Standards Agency, attached to these comments, found no Salmonella in eggs and traces on the shells of just nine eggs out of 28,000 tested (0.032 percent). Also attached are releases from the British Egg Industry Council and the Food Standards Agency that discuss results of the study.

***What cleaning and disinfection practices are common?**

Following are responses to survey questions on cleaning and disinfection –

- 36 wet clean only
- 5 dry clean only
- 9 dry and wet clean

In the surveys returned, wet cleaning or a combination of dry and wet cleaning is much more common than dry cleaning only. Of those who reported both dry and wet cleaning, other information in the surveys indicate that a combination is frequently used. It is probable that some vary the method depending on the season, particularly in northern climates where freezing weather is an issue.

Methods of disinfection and disinfectants reported include –

- Thermal fogging
- Fogging
- Pressure sprays
- Phenolic compounds
- Quaternary ammonia compounds

Seven survey respondents also fumigate after cleaning and disinfection is completed and before placement of a new pullet flock.

***Are measures taken to reduce the prevalence of rodents and pests in the pullet rearing houses?**

Forty survey responses reported on their rodent and pest control programs. This was previously discussed under biosecurity measures. Most respondents have pest and rodent control programs that include cleaning and maintenance of facilities and perimeter grounds, buffer zones on the outside of buildings, bait stations, and monitoring programs that dictate adjustments when as necessary. These adjustments can include changes in the type of baits used, the number and placement of bait stations, and additional building security. Several respondents reported protocols that require the immediate clean-up of feed spills.

UEP commends FDA for its efforts to seek information about existing practices to control SE during pullet rearing before proceeding with rule making. Thank you for your consideration of the information presented in these comments.

Sincerely,

Howard M. Magwire
Director of Government Relations

Attachments